K120168

MAY - 2 2012

Premarket Notification 510(k) Summary
As required by section 807.92

Lullaby™ LED Phototherapy System

GENERAL COMPANY INFORMATION as required by 807.92(a)(1)

Date:	10th January 2012
Submitter:	Wipro GE Healthcare Private Ltd. 4, kadugodi industrial area bangalore, INDIA 560067
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Secondary Contact Person:	Sanjukta DebRoy GE Healthcare, Phone : +91 9632211022 Fax :+9180 28411645
Device: Trade Name:	Lullaby™ LED Phototherapy System
Common/Usual Name:	Phototherapy Device
Classification Names:	Neonatal Phototherapy Unit ,
Product Code:	General Hospital, LBI,
Regulation No:	21 CFR 880.5700 Unit, Neonatal Phototherapy
Predicate Device(s):	Lullaby™ Phototherapy System (K071828)
Device Description:	The Lullaby™ LED Phototherapy System is intended for the treatment of neonatal hyperbilirubinemia, commonly known as neonatal jaundice, in a hospital. The system can be used for infants in a bassinet, incubator, open bed or radiant warmer. The lamp unit emits blue light, which falls within the phototherapy therapeutic spectrum range. The Lullaby™ LED Phototherapy System consists of a lamp unit with 10 blue LED lamps mounted on a roll stand. The lamp unit consists of a lightweight plastic light enclosure. It can be adjusted vertically and tilted if required. The light enclosure can be tilted up to approximately 90° from the horizontal about it pivot axis. The height of the pedestal can be adjusted to change the vertical position of the lamp unit. The base of the Lullaby™ LED Phototherapy System is designed to slide conveniently under a bassinet, incubator, open bed, or radiant warmer. The lamp unit is designed as a table top style to place directly on the incubator

Indication for Use:

The Lullaby™ LED Phototherapy System is used for the treatment of indirect hyper-bilirubinemia in term and pre-term infants, in a hospital environment – NICUs, PICUs and Well-baby Nurseries - administered by trained, professional medical staff, on the order of a licensed medical practitioner.
The Lullaby™ LED Phototherapy System is intended for use under the direct supervision of a licensed healthcare practitioner.
The Lullaby™ LED Phototherapy System device is not intended to be operated in mobile vehicles including ambulances or other vehicles associated with health care facilities.

Technology:

Lullaby™ LED Phototherapy System is an intensive Phototherapy device with Blue LED light in the range of 400-550nm. This range corresponds to the spectral absorption of light by bilirubin and is thus considered to be the most effective for the degradation of bilirubin.
Blue LEDs do not emit significant energy in the ultraviolet (UV) region of the spectrum, and so there is no unusual threat of exposure of the infant to UV radiation.
In addition, blue LEDs do not emit significant energy in the infrared (IR) region of the spectrum, and so there is no unusual threat of exposure of the infant to IR radiation, or of excessive warming of the infant.
As with all phototherapy lights, protective eyeshades must be used to protect the infant's eyes from excessive light exposure during treatment.
The Lullaby™ LED Phototherapy System employs the same fundamental scientific technology as its predicate device Lullaby™ Phototherapy System (K071828) by having the same mode of action for treating neonatal jaundice.
But the source of light in Lullaby™ LED Phototherapy System is from LED source as compared to CFL source in Lullaby™ Phototherapy System.
Refer to the comparison table below for more details.

Performance Factors	**Lullaby™ Phototherapy System K071828 Predicate**	**Lullaby™ LED Phototherapy System Proposed**
Light Intensity	High Irradiance Mode: 30 $\mu W \cdot cm^{-2} \cdot nm^{-1}$ Low Irradiance Mode: 20 $\mu W \cdot cm^{-2} \cdot nm^{-1}$	High irradiance mode: > 45 $\mu W \cdot cm^{-2} \cdot nm^{-1}$ Low irradiance mode: > 22 $\mu W \cdot cm^{-2} \cdot nm^{-1}$
Light Spectrum	450-475 nm	450-465 nm
Surface Area Coverage	60 cm X 30 cm	50 cm X 30 cm
Power Consumption	100W	20W (Low power consumption because of use of LED lights)
Lamp Life	1000 hours	50000 hours
Lamp Source	CFL tubes	LEDs
Overheat protection	Power cutoff for temp > 90° C	Power cutoff for temperature ≥ 85° C

Determination of Substantial Equivalence:	Summary of Non-Clinical Tests: Verification and Testing activities establish the performance, functionality, usability, safety, and reliability characteristics of Lullaby™ LED Phototherapy System. The Lullaby™ LED Phototherapy System comply with voluntary standards as detailed in Section 09, 17 and 18 of this premarket submission. The following quality assurance measures were applied to the development of the system: • Risk Analysis • Requirements Reviews • Design Reviews Summary of Simulated Use Setting: The Design verification of Lullaby™ LED Phototherapy System has been divided into several protocols that include electrical, mechanical, safety Testing, reliability, and system design verification protocols. The performance testing included testing on unit level, system level, as well as usability and safety parameters. The results of the Design verification testing protocols have been documented in Section 18 of this 510(k) application. The results demonstrate that the Lullaby™ LED Phototherapy System meets all design requirements and performance claims. The subject of this premarket submission, Lullaby™ LED Phototherapy System, did not require clinical studies to support substantial equivalence.
Conclusion:	GE Healthcare considers the Lullaby™ LED Phototherapy Systems to be as safe and as effective as the predicate device, and the performance to be substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Wipro GE Healthcare Private Ltd.
C/O Ms. Agata Anthony
Regulatory Affairs Director
Ohmeda Medical
8880 Gorman Road
Laurel, Maryland 20723

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Re: K120168
Trade/Device Name: Lullaby™ LED Phototherapy System
Regulation Number: 21 CFR 880.5700
Regulation Name: Neonatal Phototherapy Unit
Regulatory Class: II
Product Code: LBI
Dated: March 3, 2012
Received: March 7, 2012

Dear Ms. Anthony:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number : K120168

Device Name: Lullaby™ LED Phototherapy System

Indications for Use:

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Prescription Use__X____ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for RJC

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

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